IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of: **Toshikazu Hirayama, et al.**

Confirmation Number: **3311**

Serial No.: **09/821,451**

Group Art Unit: **3763**

Filed: **April 3, 2001**

Examiner: **Ann Lam**

For: **DRUG SYRINGE**

Attorney Docket: **010477**

APPEAL BRIEF

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Date: **January 21, 2004**

Sir:

A Notice of Appeal was filed on December 17, 2003. A check is attached. Any needed additional fees may be charged to Deposit Account No. 01-2340. This Brief is in response to the final Office Action mailed on September 24, 2003.

REAL PARTY IN INTEREST

The real parties in interest are (1) Nissho Corporation, 9-3, Honjonishi 3-chome, Kita-ku, Osaka-shi, Osaka 531-0073 Japan, and (2) Sunstar, Inc., 3-1, Asahimachi, Takatsuki-shi, Osaka 569-1044 Japan.

RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

STATUS OF CLAIMS

Claims 2 and 6 were canceled and claims 1 and 3-5 are pending, rejected, and on appeal.

STATUS OF AMENDMENTS

All amendments are entered.

SUMMARY OF INVENTION

Claim 1 recites

A drug syringe comprising:

a barrel which is provided with a nozzle mounting portion at a distal end thereof;

a plunger which is provided with a gasket capable of sliding hermetically along an inner wall of the barrel at a distal end thereof and inserted from a proximal end of said barrel;

The Appellants' exemplary syringe (Figs. 1 or 2) is used in the field of treating periodontal disease by injecting drugs between the tooth and the gum (specification page 1, lines 20-24). Such drugs are not extremely viscous and the plunger 2 includes a gasket 21typically formed from elastic rubber material (page 6, line 21) to prevent the liquid drug from squirting out between the plunger 2 and the barrel 1. The barrel includes a flange 12 which is gripped by the fingers (page 5, line 23) to force the plunger 2 into the barrel 1. Claim 1 continues,

and a nozzle which is freely detachable with said nozzle mounting portion, said nozzle including a mounting portion on the proximal end side which is provided with means for mounting to said nozzle mounting portion and a discharging portion which extends bending at a predetermined angle from this mounting portion,

The bend at a predetermined angle is illustrated in the drawing, which also show two different mounting portions. Fig.1 shows a mounting portion in which female threads for mounting the nozzle 3 to the barrel 1 are integrally formed with the barrel (this feature is recited in claim 4), and Fig. 2 shows a mounting portion in which the female threads are in a collar that is freely rotatable around the barrel (recited in claim 5). These features are explained in the specification between page 5, line 26 and page 6, line 14. Claim 1 continues,

> *wherein said discharging portion located at a distal end side of a bended portion of said nozzle is formed so as to become thinner at a tip thereof in a tapered shape.*

This taper feature is shown in the drawing and is described at page 7, line 13 in the specification.

Claim 3 depends from claim 1 and recites the structure of the mounting portion in more detail. According to claim 3, the barrel includes a distal end tip (111 in Figs. 1-2; described at page 6, line 1) which mates with the inner cavity or bore 312 of the nozzle 3, and the nozzle-mounting portion 11 of the barrel has female threads 112 that screw together with male threads 311 on the proximal end of the nozzle (page 5, line 26 to page 6, line 5). Claim 3 recites that the structure comprises a luer lock.

Claim 4 recites that the female threads 112 are integrally formed with the barrel 1; this is shown in Fig. 1.

Claim 5, in contrast with claim 4, recites that the female threads 112 are freely rotatable around the barrel 1. This feature is shown in Fig. 2 and is described at page 6, line 7. The free rotation of the female-threaded member permits the nozzle 3 to be mounted on the barrel 1 at any rotational angle. Claim 5 reads:

The drug syringe according to claim 3, wherein the female threads are disposed in a freely rotatable condition on the outer wall of the barrel.

The feature of claim 5 is useful for the following reason: The user pushes the plunger 2 with the thumb while the fore and middle fingers are wrapped around the protruding portions of the flange 12, so the orientation of the barrel 1 relative to the hand is generally fixed. With the feature of claim 5, the nozzle 3 can be set at any angle on the barrel 1, and then secured at the chosen angle by rotating the female-threaded member around the barrel to screw together the female threads 112 and the male threads 311 (page 6, lines 9-11). The nozzle is selectable as to bending angle and length (page 7, lines 16-20), so the user has control over the angle of the nozzle in two directions: the angle around the barrel and the anglerelative to the line of the barrel.

The Appellants note this advantage in the last paragraph of their Description (page 8, line 7): "As is clear from the above explanation, it is possible to select a nozzle of the appropriate size and bending angle in accordance with the state of the injection region of a patient at time of use by using the drug syringe of the present invention."

GROUPING OF CLAIMS

Claims 1 and 5 should be considered independently (should not stand or fall together); this is argued for below.

ISSUES

(i) Whether claims 1, 3, and 4are anticipated under 35 U.S.C. §102(e) by Discko, Jr., U.S. Patent 5,267,859 ("Discko").

(ii) Whether claim 5 is anticipated under 35 U.S.C. §102(e) by Discko.

ARGUMENT: GROUPING OF CLAIMS

Claims 1 and 5 should be considered independently because claim 5 recites an additional feature which is not disclosed by the Discko reference and which relates to the angular relationship of the nozzle. As is discussed further below, Discko's cartridge 12, which contains the material to be extruded and a piston, corresponds to the body of an ordinary syringe but it is mounted in the end of a "barrel" 16 (Fig. 1) and has a circular rear flange 26 (Fig. 2) to lock into the barrel; the angle of the nozzle relative to the flange 26 is immaterial and arbitrary.

ARGUMENT: REJECTION OF CLAIMS 1, 3, AND 4 OVER DISCKO

(1) Discko was first applied in the Final Office Action of October 23, 2002. The Appellants argued against Discko (in the Amendment After Final Rejection of February 24, 2003), resulting in withdrawal of the rejection over Discko '859. Now, the Examiner again rejects the identical claims over Discko, and the new rejection is nearlyidentical to the rejection of October 23, 2002.

As the present rejection was already overcome earlier in the prosecution, the repeated rejection is believed not to conform with the requirement of 37 C.F.R. § 1.104(a)(1), which requires the Examiner "[o]n taking up an application" to conduct an examination which is "complete with respect ... to the patentability of the invention." The honorable Board is solicited to consider whether an examiner may recycle a rejection in the manner of this case, to the detriment and delay of the Applicants' cause, within the Rules. Repeating a rejection that was already overcome, if it is allowed, can prolonged the prosecution arbitrarily, contrary to the spirit and implication of 37 C.F.R. § 1.104(a)(1). If an examiner is incapable of coming up with a *new* rejection, then perhaps the case should be allowed; the Board's opinion is requested.

(2) Discko discloses a cartridge 12 with a nozzle 32 (Fig. 2). The rear flange 26 of the cartridge 12 locks it to the gun or syringe 10 which includes a barrel 16 (Fig. 1; col. 3, line 10). The syringe 10 is worked "so that the plunger tip 22 forces the material contained within cartridge 22 out of the nozzle 32" (col. 3, line 14).

The Examiner identifies the cartridge 12 with the claimed nozzle (fourth line of the last paragraph on page 2 of the Office Action) and states that it is removable from the barrel 16. However, the cartridge 12 does not correspond to the Appellants' claimed nozzle.

Discko discloses a barrel, but Discko's "barrel" does not correspond to the Appellants' claimed "barrel," nor to any other feature recited in the Appellants' claims; it is most analogous, perhaps, to the hand of the person using the Appellants' syringe. Fig. 2 shows that it is Discko's *cartridge 12* which has:

- a cylindrical body portion 30 (col. 3, line 59);
- a piston 28 inserted into the open end 42 of the cartridge (Fig. 2);
- a nozzle 32 (col. 3, line 16); and
- a mounting portion (rear flange 26, col. 3, line 58) at the end of the body portion 30 opposite to the nozzle 32. Discko's Figs. 4 and 5 show other embodiments which are very similar to that of Fig. 2, and have similar enumeration (nozzle 32 in Fig. 2 corresponds to nozzles 232 and 332 in Figs. 4 and 5, respectively).

Discko does not anticipate, because Discko nowhere discloses that the nozzle 32 is removable from the body portion 30, contrary to the fourth paragraph of claim 1 which recites that the nozzle is "freely detachable."

The one-piece construction of the cartridges is evident from the cross-section hatching in Figs. 3-5, and Discko's statement that the cartridge is "made from clear nylon or polypropylene" (col. 3, line 50), implying that the cartridge is molded of those materials.

(3) The Examiner asserts that Discko's plunger 20 is provided with a gasket capable of sliding hermetically, but the Appellants see none. There is no description of any gasket inside the cartridge, where it might be of use.[1] The piston 28 has no gasket, and apparently does not need one because the material M is "viscous" (col. 3, line 22), and apparently so viscous that if must be forced into the cartridge by a screw mechanism (Figs. 9-10 and col. 6, line 67 to col. 8, line 12).

Moreover, the dental material M is not filled in the barrel 16. It would be pointless to make the inner wall of *barrel* hermetically slidable, and Discko makes no such suggestion. Only in the *cartridge* would this make sense.[2] The plunger cannot be adapted to hermetic sliding.[3]

ARGUMENT: REJECTION OF CLAIM 5 OVER DISCKO

Claim 5 depends from claim 3 and incorporates its subject matter. The Examiner asserts that the threads recited in claims 3 and 5 are anticipated by Discko's Fig. 1, but the Appellants respectfully point out that the only helical structure shown in Fig. 1 is a spring at the rear end of the plunger 20.

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1 Discko discloses that a dental material M is filled into the body portion 30 of the cartridge 12, and that a piston 28 is advanced by the tip 22 of a plunger 20, so that the material M is squeezed out (col. 3, lines 12-16; col. 4, lines 53-55; and col. 5, lines 3-5).

2 "In use, the dentist places the dental material M in the open end of cartridge 12," writes Discko at col. 4, line 19. Discko then continues at line 25, "the dentist places a plug or piston 28 sealing the open end 22." The piston 28 is shown through a cut-away in Fig. 2; above, "open end 22" should read "open end *42*," see col. 3, lines 15 and 59.

3 The plunger tip 22, which comprises much or all of the length of the plunger 20 that could be inserted, is tapered and does not appear to be adapted for sealing, while the cylindrical part of the plunger 20 is too large in diameter to fit inside the cartridge 12; Fig. 1 shows that the outside diameter of the plunger 20 is a least as great as the outside diameter of the cartridge 12, which must of course be greater than the inside diameter of the cartridge 12. Conversely, Figs. 4-5 show that the plunger tip is too small in diameter to slide hermetically. These figures show that the piston is pushed by the plunger tip 22 or 222. The action of tip 222 is described at col. 4, line 53: "The piston 242 is advanced by plunger tip 222 to extrude the material."

For the reasons above, the rejections should be reversed, which is requested.

Respectfully submitted,

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APPENDIX—CLEAN VERSION OF CLAIMS

1. (original): A drug syringe comprising:

a barrel which is provided with a nozzle mounting portion at a distal end thereof;

a plunger which is provided with a gasket capable of sliding hermetically along an inner wall of the barrel at a distal end thereof and inserted from a proximal end of said barrel; and

a nozzle which is freely detachable with said nozzle mounting portion, said nozzle including a mounting portion on the proximal end side which is provided with means for mounting to said nozzle mounting portion and a discharging portion which extends bending at a predetermined angle from this mounting portion,

wherein said discharging portion located at a distal end side of a bended portion of said nozzle is formed so as to become thinner at a tip thereof in a tapered shape.

2. (canceled)

3. (original): The drug syringe according to claim 1,

wherein the nozzle mounting portion comprises a distal end tip that engages with the inner cavity of the nozzle and female threads which are disposed concentrically on the outside of the distal end tip, and said female threads are constituted so as to screw together with male threads disposed on the proximal end of the nozzle, and the nozzle mounting portion of the nozzle and the nozzle mounting portion of the barrel are formed so as to comprise a luer lock.

4. (original): The drug syringe according to claim 3, wherein the female threads are integrally formed with the barrel.

5. (original): The drug syringe according to claim 3, wherein the female threads are disposed in a freely rotatable condition on the outer wall of the barrel.

6. (canceled)